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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,766	06/02/2006	Michael H. Bracey	TSRI 923.1	8883
2387	7590	05/14/2008		
Olson & Cepuritis, LTD. 20 NORTH WACKER DRIVE 36TH FLOOR CHICAGO, IL 60606			EXAMINER STEADMAN, DAVID J	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 05/14/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,766	<b>Applicant(s)</b> BRACEY ET AL.	
	<b>Examiner</b> David J. Steadman	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Status of the Application***

**[1]** Claims 1-39 are pending in the application.

**[2]** Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, and a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, all filed on 9/27/07, is acknowledged. *In order to perfect sequence compliance and in the interest of compact prosecution, applicant should submit a formal amendment directing entry of the substitute sequence listing paper copy into the specification.*

### ***Election/Restriction***

**[3]** Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I**, claim(s) 1-2, drawn to the special technical feature of a crystallized mammalian FAAH.

**Group II**, claim(s) 3, drawn to the special technical feature of a 3-D model of FAAH.

**Group III**, claim(s) 4, drawn to the special technical feature of a method for determining the 3-D structure of FAAH.

**Group IV**, claim(s) 5, drawn to the special technical feature of a method for determining the molecular structure of a molecule or complex of unknown structure.

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**Group V**, claim(s) 6-8, drawn to the special technical feature of a method for identifying an agent that interacts with an internal channel of FAAH, including the active site.

**Group VI**, claim(s) 6 and 9-11, drawn to the special technical feature of a method for identifying an agent that interacts with an internal channel of FAAH, including the substrate binding pocket.

**Group VII**, claim(s) 6 and 12-13, drawn to the special technical feature of a method for identifying an agent that interacts with an internal channel of FAAH, including the membrane port.

**Group VIII**, claim(s) 6 and 14-15, drawn to the special technical feature of a method for identifying an agent that interacts with an internal channel of FAAH, including the cytosolic port.

**Group IX**, claim(s) 6 and 16-17, drawn to the special technical feature of a method for identifying an agent that interacts with an internal channel of FAAH, including the dimerization tunnel.

**Group X**, claim(s) 6 and 18-19, drawn to the special technical feature of a method for identifying an agent that interacts with an internal channel of FAAH, including the membrane binding domain.

**Group XI**, claim(s) 6 and 20-21, drawn to the special technical feature of a method for identifying an agent that interacts with an internal channel of FAAH, including the head group tunnel.

**Group XII**, claim(s) 6 and 22-23, drawn to the special technical feature of a method for identifying an agent that interacts with an internal channel of FAAH, including the alkyl tunnel.

**Group XIII**, claim(s) 24-25, drawn to the special technical feature of a method for determining the 3-D structure of FAAH and a method for identifying an agent that interacts with the SH3 binding domain of FAAH.

**Group XIV**, claim(s) 26-27, drawn to the special technical feature of a method for determining the 3-D structure of FAAH and a method for identifying an agent that interacts with the surface helix-loop-helix of FAAH.

**Group XV**, claim(s) 28-29, drawn to the special technical feature of an agent and a pharmaceutical composition thereof.

**Group XVI**, claim(s) 30-33, drawn to the special technical feature of a method for treating a pathological condition.

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**Group XVII**, claim(s) 34-35, drawn to the special technical feature of a method for screening an agent for ability to modulate FAAH activity.

**Group XVIII**, claim(s) 36, drawn to the special technical feature of a method for engineering FAAH variants with altered substrate specificity.

**Group XIX**, claim(s) 37-38, drawn to the special technical feature of a method for altering membrane tropism.

**Group XX**, claim(s) 39, drawn to the special technical feature of a method for engineering FAAH variants with altered membrane binding properties.

**[4]** The technical feature linking groups I-XX is a FAAH polypeptide. The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The crystal of Group I, the model of Group II, the methods of Groups III-XIV and XVI-XX, and the agent of Group XV share no special technical feature as, for example, the model of Group II encompasses models of FAAH other than models of the FAAH of the crystal of Group I and the FAAH polypeptides of Groups XV-XVII encompass FAAH polypeptides other than the FAAH of the crystal of Group I.

According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions of Groups I-XX do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is a crystallized mammalian FAAH, which can be broadly but reasonably interpreted as a frozen mammalian FAAH polypeptide, present in an ice crystal. Mammalian FAAH polypeptides are well-known in the prior art (see, *e.g.*, Patricelli et al. *Biochemistry* 2001:6107-6115, 2001; cited in the IDS filed on 4/16/07) and it would have been obvious to one of ordinary skill in the art to freeze a stock solution of mammalian FAAH for later use and thus does not make it a contribution over the prior art. Patricelli also teaches engineered mutants of FAAH with altered substrate specificities and acknowledges that FAAH polypeptides are used to screen agents for the ability to modulate FAAH activity.

**[5]** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**[6]** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Notice of Possible Rejoinder***

**[7]** The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

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claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/  
David J. Steadman, Ph.D.  
Primary Examiner  
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